

COMPONENT E-H WITH TYLAN- testosterone propionate, estradiol benzoate and tylosin tartrate implant
Elanco Animal Health Co

Elanco™
Component®

Heifers

E-H with Tylan®

(testosterone and estradiol and tylosin implant)

Each implant consists of 200 mg testosterone progesterone USP and 10 mg estradiol benzoate and 29 mg tylosin tartrate

HEIFER IMPLANTS

20 dose Cartridge Belt

Use with a Component Planter

For Use In Animals Only

DESCRIPTION:

Each cartridge belt holds 20 doses of Component E-H with Tylan (testosterone and estradiol and tylosin implant)Implants. Each dose of 9 pellets consists of 8 pellets containing a total of 200 mg testosterone propionate USP and 20 mg estradiol benzoate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. Component E-H (testosterone and estradiol implant) Implants are recommended for use in heifers weighing 400 lbs or more for INCREASED RATE OF WEIGHT GAIN AND IMPROVED FEED EFFICIENCY.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

DOSAGE:

Administer 1 implant per animal according to the following instructions.

GENERAL INSTRUCTIONS:

Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and planter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 9 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

A withdrawal period has not been established for this product in pre-ruminating calves.

Do not use in calves to be processed for veal.

RESTRICTED DRUG (CALIFORNIA) — USE ONLY AS DIRECTED —
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —
KEEP OUT OF REACH OF CHILDREN

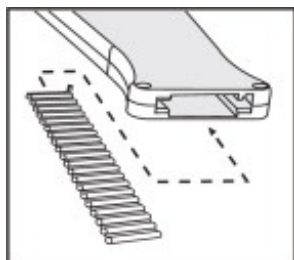
CAUTION:

For use in heifers only. Bulling, vaginal and rectal prolapse, udder development, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with testosterone propionate and estradiol benzoate.

IMPLANTING INSTRUCTIONS:

Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.



Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with a germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.



Implant the Pellets

After inserting the needle fully in the correct position, squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain and may lead to undesirable side effects such as noted in the CAUTION.

Clean the Needle

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

Storage Conditions

Store at controlled room temperature 15° to 30°C (59° to 86° F) DO NOT refrigerate – avoid excessive heat and humidity. Discard open foil pouches.

NADA 135-906, Approved by FDA

Manufactured by a non-sterilizing process.

Component E-H with Tylan (testosterone and estradiol and tylosin implant) is covered by U.S. Patent No. 5,874,098

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Distributed by Elanco Animal Health, a Division of Eli Lilly and Company, Indianapolis, IN 46285, USA

To report adverse events, access medical information, or to obtain additional product information, call 1-800-428-4441

PA086880AMX
AH0338

Principal Display Panel - Pouch Label

Elanco™

Component®

Heifers

E-H with Tylan®

(testosterone and estradiol and tylosin implant)

One 20-Dose Cartridge Belt

Elanco™

Component®

E-H with Tylan™

HEIFERS

(testosterone and estradiol and tylosin implant)

Each implant consists of 200 mg testosterone propionate USP and 20 mg estradiol benzoate and 29 mg tylosin tartrate

HEIFER IMPLANTS

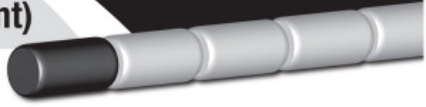
Indications: Component E-H with Tylan (testosterone and estradiol and tylosin implant) Implants are recommended for use in heifers weighing 400 lbs. or more for increased rate of weight gain and improved feed efficiency. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

Contains: One cartridge belt of 20 implants each sealed in a sanitary foil pouch. Each dose consists of testosterone propionate USP 200 mg and estradiol benzoate 20 mg with 29 mg tylosin tartrate as a local antibacterial.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions.

Manufactured by a non-sterilizing process.

NADA 135-906, Approved by FDA



TAKE TIME
OBSERVE LABEL
DIRECTIONS

TEAR HERE

One 20-Dose Cartridge Belt

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A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

RESTRICTED DRUG (CALIFORNIA) — USE ONLY AS DIRECTED — FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN

Caution: For heifer use only. Bulling, vaginal and rectal prolapse, udder development, ventral edema and elevated tail-heads have occasionally been reported in heifers implanted with testosterone propionate and estradiol benzoate.

Important: Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

Store at controlled room temperature: 15° to 30°C (59° to 86°F)

DO NOT refrigerate — avoid excessive heat and humidity. Discard open foil pouches.


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PURCHASE SEAL 20 IMPLANTS



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EXP

LOT

Principal Display Panel - Carton Label

Elanco™

Component®

Heifers

E-H with Tylan®

(testosterone and estradiol and tylosin implant)

100 IMPLANTS

Inactive Ingredients

Ingredient Name			Strength	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
METHYL ALCOHOL (UNII: Y4S76JWI15)				
WATER (UNII: 059QF0KO0R)				
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0986-0338-29	5 in 1 CARTON		
1		1 in 1 POUCH		
1		20 in 1 CARTRIDGE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA135906		12/09/2013	

Labeler - Elanco Animal Health Co (807447169)

Establishment

Name	Address	ID/FEI	Business Operations
Ivy Animal Health Inc		088106096	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia and Upjohn Company		829076566	API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Gedeon Richter Plc.		644781932	API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Bayer Pharma AG		341322131	API MANUFACTURE